No. 83-1925

in the

Supreme Court

of the

United States

OCTOBER TERM, 1983

HILLSBOROUGH COUNTY, FLORIDA AND
HILLSBOROUGH COUNTY HEALTH DEPARTMENT,

vs.

AUTOMATED MEDICAL LABORATORIES, INC.

ON APPEAL FROM THE UNITED STATES COURT
OF APPEALS FOR THE ELEVENTH CIRCUIT

APPELLEE'S MOTION TO AFFIRM

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On the Brief

June 26, 1984.

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APPELLEE'S MOTION TO AFFIRM

Appellee, AUTOMATED MEDICAL LABORATORIES, INC. ("AML"),[1] moves, pursuant to Sup.Ct.R. 16.1(c), to affirm the judgment of the United States Court of Appeals for the Eleventh Circuit on the grounds that the Circuit Court's resolution of the matter was so

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[1]Pursuant to Sup.Ct.R. 28.1, the following is a list of subsidiaries (except wholly owned subsidiaries) and affiliates of AML: Dialysis Corporation of America (subsidiary of AML), Viragen, Inc. (subsidiary of AML), Florida Immunological Institute, Inc. (subsidiary of Viragen, Inc.).

eminently correct as to warrant affirmance by this Court, and that the resolution of the questions presented requires no further argument. *Equitable Life Assurance Society v. Brown*, 187 U.S. 308, 311 (1902); *Hicks v. Miranda*, 422 U.S. 332, 343-345 (1975).

STATEMENT OF FACTS AND PROCEEDINGS BELOW

This is a direct appeal, pursuant to 28 U.S.C. §1254(2), from the judgment and opinion entered on January 16, 1984 by the United States Court of Appeals for the Eleventh Circuit, holding that Hillsborough County Ordinances 80-11 and 80-12, and the rules and regulations promulgated thereunder, are preempted by federal regulation, and, therefore, violative of the United States Constitution.

On November 26, 1980, Appellant, HILLSBOROUGH COUNTY, FLORIDA ("County"), adopted Ordinances 80-11 and 80-12, purporting to regulate plasmapheresis establishments and the eligibility of donors of blood plasma.[2] Ordinance 80-11 imposed a license tax on blood plasma centers, and required licensees, among other things, to permit inspection of blood plasma centers by Appellant HILLSBOROUGH COUNTY HEALTH DEPARTMENT ("Department"). Ordinance 80-11, in addition, required blood plasma centers located within Hillsborough County to provide continuously updated

[2]Plasmapheresis is a process whereby, during a single procedure, blood is removed from a human donor, the plasma is removed from the whole blood, and the red blood cells are returned to the donor. The text of the subject ordinances and rules and regulations appears at pages A-29 through A-42 of the Jurisdictional Statement.

information to the Department regarding their ownership, employees, equipment, and facilities.

Ordinance 80-12, and the rules and the regulations promulgated thereunder, required that a blood plasma donor, prior to donating plasma, undergo a medical examination and obtain a certificate of good health, and to obtain from the Department an identification card, which identification card would have permitted the potential donor to undergo plasmapheresis for a period of six months only, and only at a single specified plasma center within Hillsborough County. Ordinance 80-12 also required a licensee plasma center to submit to the Department, on a daily basis, and as to each procedure performed, detailed information regarding the donor, reports of testing, and results of the procedures, and to pay to the Department a fee of $1.00 for each procedure performed.

AML, a Florida corporation that, through a wholly owned subsidiary corporation, operates a blood plasma center in Tampa, Hillsborough County, Florida, filed a civil action against the County and the Department in the United States District Court for the Middle District of Florida, challenging the constitutionality of the Ordinances. AML's complaint challenged the County regulatory scheme on the grounds that it was preempted by regulations of the United States Food and Drug Administration ("FDA"), (21 C.F.R. Subchapter F—"Biologics"), that it imposed an undue burden on interstate commerce, that it denied AML its right to equal protection of the law, and for other reasons.

After a non-jury trial, the United States District Court for the Middle District of Florida entered its

opinion and final judgment, on November 1, 1982, holding §7 of Ordinance 80-12 and §4 of the rules and regulations (dealing with required breathalyzer tests) unconstitutional, as impermissibly burdening interstate commerce, and upholding the remainder of the County regulatory scheme (Jurisdictional Statement, pp. A-13 through A-20).

AML appealed to the United States Court of Appeals for the Eleventh Circuit, and the County cross-appealed with respect to the portions of the Ordinances invalidated by the District Court.

The American Blood Resources Association (the national trade association for the plasmapheresis industry) and the Florida Association of Plasmapheresis Establishments participated as *amici curiae* in the appeal in support of AML's position.[3]

The *amici* filed a brief explaining the manner in which the challenged County regulatory scheme frustrated national policy expressed in the FDA regulations by, among other things, creating conflicting standards of

[3]The motion by American Blood Resources Association and the Florida Association of Plasmapheresis Establishments to file their *amici* brief in support of AML's position was not opposed in a timely manner. The suggestion in the Jurisdictional Statement (page 4) that the participation of the *amici* in the appeal was unfair or prejudicial to Appellants is without merit. The issue of preemption was in the case from the day AML's complaint was filed, and the issue was addressed by the District Court, by the panel of the Eleventh Circuit at oral argument, by the Eleventh Circuit in its opinion and by the County in its petition for rehearing. There has been no lack of fairness in the proceedings below. In any event, such an issue cannot be before this Court on this direct appeal pursuant to 28 U.S.C. §1254(2).

donor eligibility, reducing plasma availability, and causing the prices of products derived from plasma to rise, to the detriment of the many people who are dependent upon the life-saving qualities of these pharmaceutical products, all without any benefits not already provided by the federal regulations.

The Eleventh Circuit held that Ordinances 80-11 and 80-12 were invalid, because the County regulatory scheme was preempted by federal regulation of the area, under the tests enunciated in *Pennsylvania v. Nelson*, 350 U.S. 497 (1956). Accordingly, the Eleventh Circuit did not decide the other questions raised on the appeal (Jurisdictional Statement, pp. A-1 through A-12; 722 F.2d 1526 (1984)).

Hillsborough County petitioned for rehearing by panel. In its petition, the County explicated its view that the Eleventh Circuit had erred in holding that federal law preempted its Ordinances, had ignored record evidence and had misapplied the law. The Eleventh Circuit denied the petition for rehearing (Jurisdictional Statement, pp. A-22 through A-26).

ARGUMENT

I. THE STANDARDS TO BE APPLIED IN DETERMINING IF LOCAL LEGISLATION IS PREEMPTED BY FEDERAL REGULATION ARE WELL SETTLED AND FREE OF DOUBT.

As recently as June 11, 1984, this Court restated the established standards for determining a claim that local legislation is invalid as having been preempted by

federal law. *Michigan Canners & Freezers Association, Inc. v. Agricultural Marketing and Bargaining Board*, _____ U.S. _____, _____ (June 11, 1984) (slip opinion, page 7):

> Federal law may pre-empt state law in any of three ways. First, in enacting the federal law, Congress may explicitly define the extent to which it intends to pre-empt state law. E.g. *Shaw v. Delta Air Lines*, _____ U.S. _____, _____ (1983). Second, even in the absence of express pre-emptive language, Congress may indicate an intent to occupy an entire field of regulation, in which case the States must leave all regulatory activity in that area to the Federal Government. *E.g. Fidelity Federal Savings & Loan Ass'n. v. de la Cuesta*, 458 U.S. 141, 153 (1982); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Finally, if Congress has not displaced state regulation entirely, it may nonetheless pre-empt state law to the extent that the state law actually conflicts with federal law. Such a conflict arises when compliance with both state and federal law is impossible, *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-143 (1963), or when the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). *See also, Fidelity Federal Savings & Loan Ass'n, supra*, at 153.

See also, Capital Cities Cable, Inc. v. Crisp, _____ U.S. _____ (June 18, 1984) (slip opinion, page 6).

Similarly, it is well settled that, in instances where no express congressional intent to preempt is found, *Pennsylvania v. Nelson*, 350 U.S. 497 (1956), provides the tests for determining if a finding of implicit congressional intent to preempt is proper.

As detailed below, the Eleventh Circuit clearly followed, and correctly applied, the controlling standards.

II. THE ELEVENTH CIRCUIT DECISION PLAINLY SHOWS A CAREFUL AND PROPER APPLICATION OF WELL SETTLED AND CONTROLLING PRINCIPLES OF LAW.

After determining that no explicit congressional intent to preempt was applicable, the Eleventh Circuit engaged in a careful analysis of the implicit preemption issue under the criteria set forth by this Court in *Pennsylvania v. Nelson, supra*, and recently reaffirmed in *Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm'n*, _____ U.S. _____, 103 S.Ct. 1713 (1983). Following that analysis, the Eleventh Circuit properly determined that Ordinances 80-11 and 80-12 are preempted by the federal regulatory system.

The Eleventh Circuit's analysis is briefly summarized as follows:

1. The federal regulation of blood and blood products is so pervasive as to make it "reasonable to infer that Congress left no room for the states to supplement it" (Jurisdictional Statement, p.A-9; 722 F.2d at 1531). Section 351 of the Public Health Service

Act (42 U.S.C. §262, "the Act") requires the licensing of each establishment producing a biological product, and requires that each such product be licensed to insure safety, purity and potency; federal regulations prescribe rules regarding blood donor suitability, testing, consent and immunization, as well as proper supervision and methods of collecting, processing and labeling blood and blood components. As more fully detailed in Point IV below, the federal regulations cover virtually every phase of the plasmapheresis process.

2. The federal interest in plasmapheresis is "dominant over any local interest" (Jurisdictional Statement, p.A-10; 722 F.2d at 1532). Congress has extensively and comprehensively regulated blood collection since 1946; the Secretary of Health, Education and Welfare has established a comprehensive "National Blood Policy," and, to that end, it employs the full range of regulatory authorities vested in the Federal Government.

3. Enforcement of Ordinances 80-11 and 80-12 would adversely affect the National Blood Policy of promoting uniformity in blood banking standards and guaranteeing a continued supply of healthy donors (Jurisdictional Statement, p.A-11; 722 F.2d at 1533). While the purpose of the County's regulation of blood plasma centers is, ostensibly, an exercise of the County's police power to safeguard residents of Hillsborough County who are plasma donors, and hence similar to that of the federal regulations,[4] the Ordinances impose

[4]Ordinance 80-12 incorporates by reference the federal regulations regarding Source Plasma (Human), which is defined as the fluid portion of human blood collected by plasmapheresis and intended as source material for further manufacturing use.

additional requirements upon the centers, requirements which clearly are covered by the federal regulations but which impose additional and unnecessary burdens and expense upon the centers.

III. EXAMINATION OF THE FEDERAL REGULATION OF THE FIELD, AND OF RECENT DECISIONS OF THIS COURT, ESTABLISH THAT THE ELEVENTH CIRCUIT CORRECTLY DECIDED THIS CASE.

Plasma harvested by the plasmapheresis procedure is manufactured into life-saving pharmaceutical products known as plasma derivatives. There are three kinds of derivatives: clotting factors, protein replacement fluids, and immunoglobulins.

A product known as "factor VIII concentrate" or "AHF" (antihemophilic factors) has dramatically changed the lives of hemophiliacs by permitting both home care (self-transfusion) and prophylactic treatment. This product has significantly reduced painful and crippling joint bleeds and has extended the life expectancy of a hemophiliac from about eleven years to nearly thirty years.

The globulins protect against diseases. For example, two such products are effective against tetanus and pertussis. Another, RH immunoglobulin, has saved thousands of infants' lives and spared tens of thousands more from brain damage.

Protein replacement fluids are used as volume expanders for persons who have suffered extensive burns or for persons who are in shock as a result of

surgery or trauma. These products have saved thousands of lives on the battlefield and elsewhere.

Plasma is also used to make reagents, typing sera and chemistry products used in clinical and hospital laboratories. Modern blood banking, clinical laboratory practice, and medical diagnosis heavily depend on these products. Organ transplants are made possible by the use of various tissue typing sera.

Plasma for these products is obtained mostly from paid donors who are paid to spend the several hours necessary to collect a unit of plasma. These donors must meet the stringent FDA requirements. The facilities in which plasmapheresis is performed must also meet stringent FDA requirements, and plasmapheresis storage and manufacturing procedures must be consistent with FDA requirements. *See generally*, 21 C.F.R. Subchapter F—"Biologics".

It is generally considered safe for plasma donors to be plasmapheresed as often as twice each week if FDA's limitations are observed.[5] These regulations are extensive and detailed. They comprehensively define requirements for establishment and product licenses, good manufacturing practices, procedures for donor safety and suitability, and standards for derivatives and reagents. *See generally*, 21 C.F.R., Subchapter F—"Biologics". (These regulations also relate to the

[5]*See, e.g.*, FDA Panel on Review of Blood and Blood Derivatives, "Human Plasma as a Source for Fractionation Products," (Draft Report No. 15, 1979); Dawson, *et. al.*, "Laboratory Findings on Long Term Plasmapheresis Donors: Protein Levels," *Plasma Forum* III 209 (American Blood Resources Association 1981).

collection of whole blood and other blood products). The FDA's regulations are directed toward, among other things, assuring that all donors provide informed consent, assuring that all donors are healthy enough to donate without risk, assuring that donors do not donate in excess of a number of times deemed safe (only five times per year for whole blood, as contrasted with approximately twice per week in the case of plasmapheresis), assuring the adequacy of the collection facilities, and assuring that the plasma is free from transmissible diseases such as hepatitis, and now Acquired Immune Deficiency Syndrome.

In promulgating these regulations, the Commissioner of Food and Drugs had in mind not only meeting the requirements of Section 351 of the Act, but also the safety of individual donors:

> The promulgation of standards for licensed Source Plasma (Human) reflected the Commissioner's determination that a high priority should be attached to assuring that the source material for a variety of licensed, fractionated products . . . should be collected in a manner to ensure the safety, purity and potency of those final products.
>
> A further rationale for establishing uniform standards for this human source material was to protect the plasmapheresis donor.
>
> . . . [C]omprehensive protection requirements must be adhered to by all plasmapheresis facilities . . ."

39 *Fed. Reg.* 26161, 26162 (1974).

In addition, FDA has recognized its obligation to "insure the availability of good quality plasma," 39 *Fed. Reg.* 18615 (1974), and the relationship between an adequate supply of plasma for use in the manufacture of the resulting pharmaceutical products and healthy donors:

> . . . [T]he standards must contain provisions to protect the health of plasma donors, to insure a continued, healthy donor population to serve as a source of plasma . . . In an indirect but no less important manner the requirements for donor protection assure . . . that there will be a continuous and healthy donor population . . . [I]nadequate donor protection practices defeat one of the major purposes of the regulations: namely, to protect plasma donors.

41 *Fed. Reg.* 10762-3 (1976).

FDA's biological product regulations were not, obviously, adopted in a vacuum. In addition to the statutory framework provided by Section 351 and the new drug provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §355, the Commissioner was working within the confines of the National Blood Policy, *see*, 39 *Fed. Reg.* 32702 (1974), which declared "the policy of the United States Government" to be, among other things,

> (7) To employ the full regulatory authorities now vested in the Federal Government and to seek such additional authority as may be necessary and appropriate for the purpose of assuring uniform adherence to the highest

> obtainable standards of practice of blood banking, including plasmapheresis and plasma fractionation.

39 *Fed. Reg.* at 32703.[6]

These statutes, the National Blood Policy, the biological products regulations, and FDA's explanation of those regulations make it clear that, contrary to the County's contention, protecting the health, safety and welfare of plasma donors, and of the recipients of products derived from plasma, is the sole responsibility of the Federal Government, and that Congress intends to occupy the entire field of plasmapheresis regulation. Indeed, this Court has characterized the "overriding purpose" of the FDCA as being "to protect the public health." *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969).

Insofar as FDA's regulations evidence ample concern for safety of both donor and recipient, they demonstrate that the Federal Government, through the FDA, is engaged in protecting and promoting the "public health,

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[6]The prior year, the Commissioner articulated a similar reason to justify a proposal requiring registration of intrastate blood banks:

> It is clear that uniform national regulation may be required with respect to manufacturing, processing and distribution of blood and blood products, not only because blood is a commodity of national significance, but also because there has been little or no State regulatory activity in this area.

38 *Fed. Reg.* 2965, 2966 (1973).

safety and welfare," as indeed it was obligated to do by acts of Congress, namely Section 351 of the Public Health Service Act and the FDCA. The interests which Hillsborough County was seeking to protect were not properly the subject of local legislation and, in any case, those interests had been carefully considered by FDA's Commissioner nearly a decade earlier when he acted to protect those very interests within the framework of the other important federal interests.

For example, cross-bleeding and its dangers (Jurisdictional Statement, p.6) were considered by the Commissioner and are the subject of federal regulation (21 C.F.R. §§640.63(c),(e); 645.65(b)(3),(4),(5),(6)). Unnecessary contamination of plasma centers by hepatitis positive plasma donors (Jurisdictional Statement, p.6) is covered by a different method than that desired by Hillsborough County, but is covered nevertheless (21 C.F.R. §640.67), and in such a way that a center that wants to produce plasma for hepatitis vaccine can do so (21 C.F.R. §610.40(d)(2),(3)), which it could not do under the County scheme. Informed consent, and assuring that donors are capable of understanding the risks involved in plasmapheresis (Jurisdictional Statement, p.6) is a specific subject of the source plasma regulations as well as a great deal of federal experience and law (21 C.F.R. §640.61). Local inspection of plasma centers (Jurisdictional Statement, p.6) merely duplicates existing federal inspection (21 C.F.R. Part 600); *see also*, 48 *Fed. Reg.* 26313 (1983), (though it presents the real risk that federal and state inspectors will impose differing requirements).

The Eleventh Circuit carefully considered the relationship between the County regulatory scheme and the federal regulations, and whether the local interests

were important enough, or sufficiently different, to justify the intrusion of the County scheme into the regulatory framework designed by the FDA. The Court properly concluded that they were neither.

Recent decisions of this Court regarding federal preemption provide additional support for the result reached by the Eleventh Circuit in the instant case. *Exxon Corp. v. Eagerton*, _____ U.S. _____, 103 S.Ct. 2296 (1983) (state pass-through prohibition of severance tax increase to first purchasers of gas preempted as to sales of gas in interstate commerce); *Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Comm'n*, _____ U.S. _____, 103 S.Ct. 1713 (1983) (federal regulation of nuclear safety preempts state legislation in that field); *Michigan Canners & Freezers Association, Inc. v. Agricultural Marketing and Bargaining Board, supra; see also, Capital Cities Cable, Inc. v. Crisp, supra.*

In its Jurisdictional Statement, the County acknowledges the comprehensiveness of federal regulation in the area of blood plasma collection (Jurisdictional Statement, p.6). The County attempts to set forth local goals, which it asserts go farther than those at the federal level: to protect residents against cross-bleeding and hepatitis contamination, to ensure that donors give informed consent, and to supplement the federal inspection process. However, as noted in detail above, and in the Eleventh Circuit's opinion, each of those goals is thoroughly addressed in, and regulated by, the federal blood collection and processing regulations. Moreover, the County scheme for attempting to meet these goals gives rise to potential conflicts between federal and

local regulation, a result which would contravene the preemption doctrine.

Moreover, Appellant's Jurisdictional Statement contains nothing that suggests specifically how the Eleventh Circuit erred, other than the assertions that preemption will not be presumed (citing *New York State Department of Social Services v. Dublino*, 413 U.S. 405 (1973)), and that legislation must be examined to determine whether federal and state regulations can coexist, and that there is a presumption against the ouster of local legislation (citing *Merrill, Lynch, Pierce, Fenner & Smith, Inc. v. Ware*, 414 U.S. 117 (1973)). These principles are correct and the cases are apt. The County overlooks, however, the critical fact that the Eleventh Circuit followed exactly the holdings of these cases.

The Eleventh Circuit made no presumptions in favor of preemption or in favor of setting aside the local legislation and it analyzed the challenged local legislation at great length to determine whether the County scheme could coexist with FDA's regulations. After a balanced, fair, and thorough analysis, the Eleventh Circuit concluded that they could not and that the local legislation must fall.

Similarly, no substantial question arises because "many other localities have recognized similar needs [for local legislation regulating plasma collection] in their communities" (Jurisdictional Statement, p.7). The County names a number of states and local governments that, according to the "Federal Department of Biologics" (sic), have plasma regulations. But the County's comfort in believing that others are also regulating plasmapheresis

is misplaced. If the legislation or regulations of those jurisdictions were before this Court, it would be apparent that most are substantially the same as the federal regulations, with few or no changes, and with no provisions which go beyond or conflict with the federal regulations. *E.g.*, Mich. Admin. Code R. 325, 2942 (1979); N.J. Admin. Code Tit. 9, §§8.5-8.8; Ohio Rev. Code Ann. §§3725.01-3725.06 (Baldwin 1982); Tenn. Admin. Comp. 1200-6-4 (1982). Although Connecticut regulates blood banks and plasma centers, *see*, Conn. Agencies Reg. 19-13-A50, we believe that there are no plasma centers operating there. The Dade County, Florida regulations are similar to those struck down by the Eleventh Circuit. In short, the existence of regulations of other jurisdictions footnoted in the Jurisdictional Statement does not demonstrate that the question presented by the County about its particular Ordinances is a substantial question.

Thus, the Eleventh Circuit decision presents no novel applications of the law of preemption, presents no arbitrary determination, and presents no unique fact situations. In sum, there is nothing suggesting that a full briefing and oral argument are merited, or that the question addressed by the Eleventh Circuit is, in its present posture, a substantial question.

CONCLUSION

The Eleventh Circuit properly determined, based upon controlling criteria set forth by this Court, that the subject Ordinances are preempted by federal regulation. The issues which Appellants attempt to raise do not justify full briefing and oral argument of this appeal. For the reasons stated herein, the judgment below should be promptly affirmed.

Respectfully submitted,

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June 26, 1984.

CERTIFICATE OF SERVICE

All parties required to be served have been served by depositing on this 27th day of June, 1984 copies of this document in a U.S. Post Office, with first class postage prepaid, addressed to counsel of record at his or her post office address as follows:

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